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Spotlight on innovation: key insights from the extracellular vesicle cluster meeting at the European Innovation Council

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ABSTRACT

The field of extracellular vesicles (EVs) is rapidly advancing, offering promising applications in diagnostics, therapeutics, and drug delivery. However, the translation of EV-based technologies to the clinic faces significant challenges related to heterogeneity, scalable biomanufacturing, and regulatory compliance. To address these issues, the European Innovation Council (EIC), in collaboration with the Horizon2020-funded BOW project, organized the “Extracellular Vesicle EIC Cluster Meeting,” bringing together researchers, startups, and regulatory stakeholders across Europe. Discussions focused on overcoming bottlenecks in EV production, standardization, and clinical readiness. Key outcomes included the need for application-specific benchmarks, robust manufacturing pipelines, and regulatory frameworks tailored to EVs. The event emphasized the importance of interdisciplinary collaboration, cooperation, and continued EU funding to drive innovation and strengthen Europe’s leadership in the EV field.

Key Words: extracellular vesicles, biomanufacturing, regulatory landscape, standardization, clinical translation.

In recent years, the field of extracellular vesicles (EV) has advanced significantly, primarily driven by the potential to use EV-based biomarkers for disease detection, bioactive therapeutic candidates for innovative treatments, and drug delivery vectors for precision medicine [1–3]. As this research continues to disclose the versatile functions and mechanisms of EVs, the global market interest in EV-based products and technologies is rapidly expanding, attracting substantial investments and stimulating interdisciplinary collaborations among researchers, healthcare professionals, and biotech companies in the field [4,5]. The interest in EVs stems not only from their biological functions, but also from the possible therapeutic and diagnostic applications [6,7]. As natural carriers of cellular information, EVs provide a non-invasive way to monitor health conditions, with potential applications in cancer detection, neurodegenerative disease diagnostics, and cardiovascular disease monitoring [2,8], ideal for long-term therapeutic use with a potential transformative effect on personalized treatment [7]. This is also because EVs can be engineered to deliver therapeutic agents directly to specific tissues, potentially enhancing the efficacy of treatments and minimizing side effects. However, the path to clinical application is filled with challenges, such as the need for scalable production methods, the need for standardized isolation processes and the need to comply with the applicable regulatory framework to bring the EV products to the market [9–14]. In this context, the European Innovation Council (EIC) acknowledged the translational potential of EV-based technologies for human health by organising the event titled “Extracellular vesicle EIC Cluster Meeting” in close collaboration with the Horizon2020-funded BOW project. The event created a vibrant stage for discussion on strategies to overcome key challenges such as those mentioned above. Through this initiative, the EIC aimed at pinning down the needs and the paths towards the empowerment of EV-based players in their quest of bringing EV-based diagnostics and therapies to the clinic. Ultimately, the aim is to leverage the social and economic potential of EV research and strategically place Europe at the forefront in this field.

Features of the EV Cluster Event

The EV Cluster event was hosted at the premises of the European Innovation Council and SMEs Executive Agency (EISMEA) in Brussels. The event gathered EIC granted projects on EVs, bringing together an assorted group of EV-focused researchers, startups, and well-established companies from across Europe, fostering a productive and open exchange on the scientific, technical and regulatory challenges that must be addressed to successfully develop clinically relevant and commercially viable EV-based solutions. Representatives of EIC Pathfinder-funded projects participating in the meeting included BOW, MIMIC-KeY, MindGAP, and GLADIATOR. The EIC Transition program was represented by the MARVEL, NEXUS, and AcouSome projects, while ACROBAT and EV-FOX represented the EIC Accelerator program (Table 1). Additionally, several renowned European experts in the EV field contributed to the discussions.

The participants emphasized the importance of fostering innovation and interdisciplinary collaboration, with a strong focus on translational research – bridging the gap between laboratory discoveries and clinical applications. The rationale behind this meeting closely aligns with that of the EIC Health Biotech portfolio approach, as described by Arzimanoglou [15]. Supporting collaborative, complementary and targeted efforts in the EV field by EIC would significantly increase the likelihood for innovative EV-based solutions to reach clinical stage and thus contribute to strengthening European research and industry in this promising field.

The discussions among participants focused on existing bottlenecks in translation of EV research, including the inherent heterogeneity, biomanufacturing challenges related to scalability, reproducibility, stability, and automation, incorporation of bioactive molecules and nanoparticles, as well as the successful integration of EV-based products into clinical practice for early diagnostic and/or therapeutic applications [14].

Heterogeneity of EVs

Participants in the meeting agreed that the heterogeneity of EVs is currently one of the most pressing challenges (Figure 1). EVs originate from various cell types and exhibit a wide range of sizes, compositions, and molecular signatures, which complicates the development of standardized robust methodologies needed for their diagnostic and therapeutic use [14,16]. Moreover, the diverse interactions of EVs with nano-objects such as protein coronas (i.e., different kinds of biomolecules that adhere to the surface of EVs in biological fluids) introduce an additional layer of complexity [17]. These interactions can potentially influence the biological activity, targeting, and clearance of EVs, especially *in vivo*, raising important questions about how we should approach the design and use of EV-based therapies [1]. In this context, one of the key questions that emerged during the discussion was whether future research should concentrate on mitigating or embracing the effects of the heterogeneity of EVs intended for clinical applications. Indeed, their intrinsic diversity could be exploited to create more personalized and targeted therapeutic approaches, tailored to specific disease states or patient profiles. However, embracing EVs heterogeneity requires a paradigm shift in their definition and evaluation. This calls for a broader and more flexible definition of criteria for EV purity, which could be linked and tailored to the EV specific biomedical function and application, rather than just on the “bare” analytical definition based on molecular composition and structure. For example, EVs intended for drug delivery may require different standards than those used as biomarkers for disease diagnosis. In this context, developing application-specific benchmarks (e.g., EV potency assay-based quality checks) is essential to ensure that EV-based therapies and diagnostics are effective, safe, and reproducible across clinical settings [10,12].

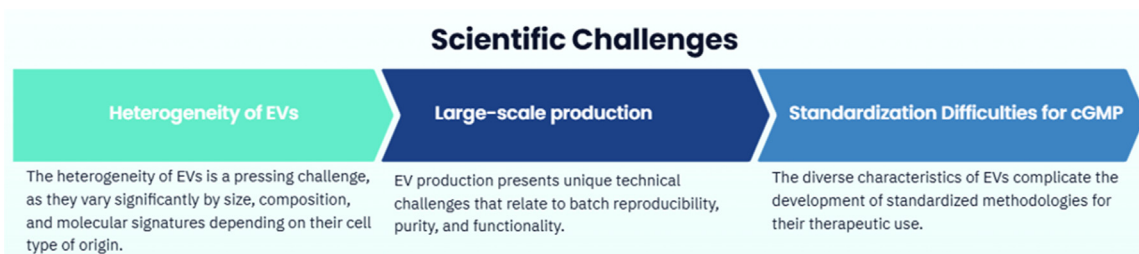


Fig. 1. Scientific and translational challenges emerged during the EIC EV Cluster meeting. (Color version of figure is available online.)

Biomanufacturing Challenges

Scalability in the EV production to meet clinical and commercial demand, in particular, represents one of the biggest challenges for the translation of EVs. Unlike traditional pharmaceuticals, EVs present unique challenges in terms of batch reproducibility and stability (Figure 1). Their inherent biological complexity and heterogeneity make it difficult to produce consistent, high-quality EV preparations on an industrial scale. Ensuring that EV batches retain consistent therapeutic properties across different production runs is crucial for both clinical efficacy and regulatory compliance [18]. Variability in the composition of EVs, including cargo, size, and membrane proteins, could result in inconsistent therapeutic outcomes, compromising and decelerating their clinical adoption. To overcome these barriers, *alternative manufacturing strategies* were discussed as potential solutions to improve both manufacturing efficiency and scalability [19]. For example, the use of *microalgae* as a renewable and sustainable source of EVs presents an alternative to traditional cell culture methods, allowing the production of large quantities of EVs, which are biocompatible and could be more easily scaled for commercial use, making them a promising candidate for future therapeutic applications [20,21]. Similarly, *3D cell culture systems* were proposed as another technique to increase EV yield and quality. These systems more accurately mimic the in vivo environment, potentially leading to more physiologically relevant EVs that are closer in nature to those produced within the human body. By optimizing these production strategies, the field could move closer to achieving the scalability required for widespread clinical and commercial use of EV-based therapies.

Furthermore, maintaining stability during production, storage, and transportation is another critical challenge. Although EVs are less sensitive to environmental conditions than cells used in cell-based therapies, they can still be affected by such conditions, and their functional integrity may degrade over time or under suboptimal circumstances. Therefore, the development of robust stabilization

techniques, a well-defined manufacturing process, a reliable potency testing strategy, and scalable analytical approaches capable of ensuring and validating EV functionality—without compromising their therapeutic potential—is paramount [9,22]. Overall, addressing these challenges requires significant advancements in *biomanufacturing processes*. At the same time, valuable lessons can be drawn from more mature examples in cell and biologics manufacturing [14]. More recently, important insights have emerged from the first successful advancements of EVs toward clinical-trial readiness. As a result, the first clinical trials have been approved in 2024 and are currently underway in Europe (EU Clinical Trials Registry numbers: 2022-500293-34-01; 2024-512498-29-00). *Automation*, scalable isolation technologies, and standardized characterization methods are all crucial components of developing a sustainable EV production pipeline adhering to *current Good Manufacturing Practices (cGMP)* (Figure 1). By overcoming the issues of batch reproducibility, stability, purity and functionality the field can move closer to the *commercial adoption* of EV-based therapies, offering new solutions for complex diseases [10,12]. Without addressing these issues, the translation of EV-based therapies from the lab to the clinic will remain constrained.

The participants finally also discussed on the opportunity offered by EV-mimicking synthetic vesicles, as they may provide advantages in scalability and reproducibility.

Regulatory Challenges

The *regulatory landscape* was also identified as one of the most critical issues (Figure 2) for the development of EV-based products. Like all biological products, also EV-based products face numerous regulatory hurdles, especially in the validation of their *potency* and *mechanisms of action*, both essential for securing market approval. The need for, and nature of potency assays as necessary part of the analytical package for process and product clearance was discussed. Because EVs are complex biological systems, demonstrating

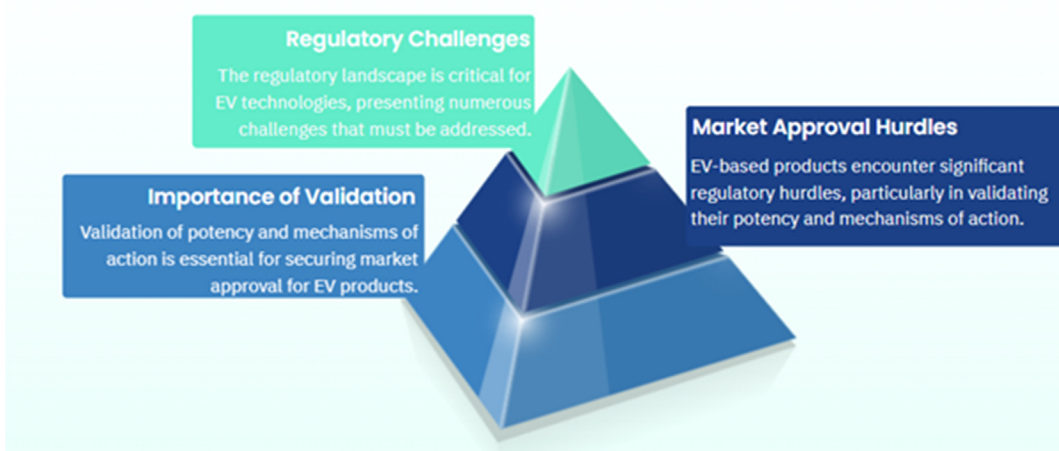
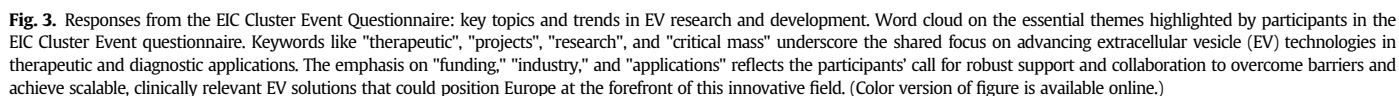


Fig. 2. Regulatory landscape for EV technologies. (Color version of figure is available online.)



EV-based therapeutics (EV-Tx) has been recognized as a critical barrier that must be overcome [4,10,12,23]. Furthermore, regulatory agencies demand clear evidence of how EVs interact with the body, their safety profile, and their intended biological effects, all of which must be thoroughly validated before EV products can enter the market. In this context, participants discussed the urgent need to clarify

Project name	Coordinator	Funding Program	Short description	Start date	End date	Budget	Website
BOW ID: 952183	CSGI	Pathfinder	Developing biomimetic mag- netic nanodevices by camouflaging them with extracellular vesicle membranes	1 November 2020	31 October 2024	4.5M €	bowproject.eu https://cordis.europa.eu/project/ id/952183
MIMIC-KeY ID: 964386	Polytechnic of Turin	Pathfinder	Mimicking EVs for their cargo transfer and homing attitude with fully artificial ones	1 June 2021	30 Nov 2025	3M €	mimickey.eu https://cordis.europa.eu/project/ id/964386
MindGAP ID: 829040	University of Coimbra	Pathfinder	Exploring EVs as biomarkers for mind-body interaction moni- toring, enabling portable diagnostics	1 April 2019	31 March 2024	4.5M €	mindgap-fet-open.eu https://cordis.europa.eu/project/ id/829040
GLADIATOR ID: 828837	University Of Cyprus	Pathfinder	Developing a theranostic plat- form for Glioblastoma Multi- forme treatment	1 January 2019	30 September 2023	6M €	https://cordis.europa.eu/project/ id/828837
MARVEL ID: 951768	CNR	Transition	Evolving reversible iMmunocap- ture by membrane sensing peptides: towARds scalable extracellular VESicles isolation	1 November 2020	30 April 2023	1.8M €	https://marvel-fet.eu/ https://cordis.europa.eu/project/ id/951768
NEXUS ID: 101058200	CNR	Transition	Scalable EV separation and manufacturing using auto- mated platforms	1 June 2022	31 May 2025	2.5M €	nexus-horizon.eu https://cordis.europa.eu/project/ id/101058200
AcouSome ID: 101099787	AcouSort AB	Transition	Developing a microfluidic mod- ule for acoustic exosome isola- tion from whole blood	1 January 2023	31 December 2025	2.5M €	acousome.com https://cordis.europa.eu/project/ id/101099787
ACROBAT ID: 190194936	EVERZOM	Accelerator	Addressing EV scalability for therapeutic applications with a focus on tissue regeneration	1 May 2022	30 April 2024	2.5M €	https://cordis.europa.eu/project/ id/190194936
EV-FOX ID: 190154762	FOX BIOSYSTEMS NV	Accelerator	Fiber-optic SPR technology for automated EV isolation and quantification from crude samples	1 July 2023	30 June 2025	3.6M €	foxbiosystems.com https://cordis.europa.eu/project/ id/190154762

and standardize the biophysical and pharmaceutical criteria of EV-Txs for regulatory purposes. Developing applicable models to streamline the biopharmaceutical characterization of EV-based drug candidates within existing regulatory frameworks would be crucial to accelerating the commercialization of EV technologies. However, current regulatory pathways—designed primarily for traditional therapies—do not yet fully accommodate the unique properties of EVs.

EV Cluster Event: Conclusions and Future Perspectives

In conclusion, the event focused on the *current status of research and development in the EV field* and emphasized the importance of bringing together EV experts from academia, industry, funding agencies for research and innovation, and regulatory bodies to foster new key collaborations at the European level aimed to address the current challenges, leverage on new opportunities and accelerate the production of EV based diagnostic and therapeutic products. A key challenge is definition of standardized regulatory protocols which would facilitate translation into clinical practice.

According to the results of a questionnaire that followed-up the EIC event (Figure 3, Table 1), "coopetition"—a cooperative form of competition where companies and research groups work together to pool intellectual property and resources was seen as a fruitful approach in the EV cluster. Another key takeaway from the event was the recognition by the participants of the *Shared Component Model* [15], as an effective way of working together to enhance the chances of success of the newly established collaborations. Additionally, as the event drew to a close, it became clear that the European EV community has the potential to drive the field forward. Finally, all participants emphasized the importance of EU funding as an essential tool to catalyze and support future research and socially impactful and responsible innovation in the field.

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Declaration of Competing Interest

None.

Author Contributions

Conceptualization: I. A., I. A., P. B., and A. B.; funding acquisition: P. B., and A. B.; methodology: G. A., P. B., A. B., and I. T.; project administration: P. B., and A. B.; resources: P. B., and A. B.; supervision: I. A., I. A., P. B., and A. B.; visualization: G. A., and I. T.; writing – original draft: G. A., P. B., A. B., and I. T.; writing – review & editing: all authors.

Supplementary materials

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